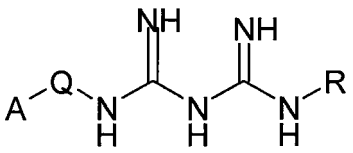
Remarks:

Favorable reconsideration is respectfully requested of the rejection of claims 39, 41, 43-45, 47-49, 51-54, 56-63 and 66 as being anticipated by Olstein (US 5,142,010).

As the Examiner has pointed out, Olstein teaches a polymeric biguanide formulation where one of the nitrogen atoms is bound by an amine linkage. As the Examiner has also pointed out, the monomer and the polymer taught by Olstein are bound to the biguanide group via a secondary amine on the biguanide. The monomer described by Olstein includes a biguanide moiety which is linked via a nitrogen atom at one terminus and has the following structure:



where A is a polymerizable group and Q is a linker (e.g. phenylene). The polymerized product will therefore be a chain with single pendant biguanide groups.

The claims of the present application have now been amended to define the application more clearly. Thus amended claim 39 reads as follows:

> A polymeric material incorporating an infection resistant biguanide-containing moiety pendant to a polymer chain, wherein the biguanide-containing moiety is chemically bound to the polymer chain though some but not all of the secondary amine nitrogen atoms of a -NH-C(NH)-NH-C(NH)-NH- biguanide group or groups of the infection resistant biguanide-containing moiety, such that a tertiary amino group remains in a bound biguanide residue.

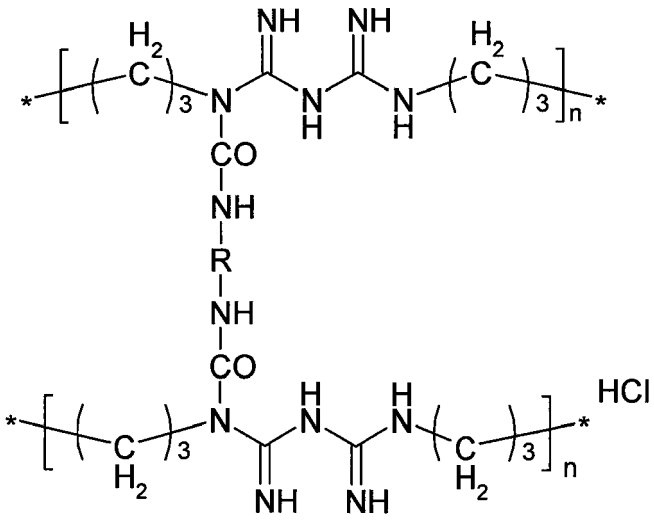
In this claim, the term "biguanide" has been replaced by "biguanide-containing moiety". Support for this change can be found throughout the specification but in particular in the passage from page 4, line 23 to page 5, line 10 where it is explained that "biguanides are strongly basic compound containing the biguanide group." The change to the claim is intended to emphasize that the moiety which is pendant to the polymer chain may, and preferably does, contain more than one biguanide group.

Furthermore, the amended claim now specifies that the biguanide-containing moiety is bound to the polymer chain through a secondary amine nitrogen atom of a biguanide group such that a tertiary amino group remains in a bound biguanide residue.

In paragraph 5 on page 3 of the Office Action, the Examiner expresses the opinion that the compound of the instant claims does not have secondary amine nitrogen atoms. However, in the present specification, on page 5, final paragraph, it is explained that he antimicrobial activity of biguanide compounds may derive from the strongly basic character of the biguanide groups which form addition salts with a cationic charge delocalized over the five neighboring secondary amine nitrogen atoms. It is therefore clear that, for the purposes of the specification, the amine nitrogen atoms of the biguanide structure are considered to be secondary amine nitrogen atoms. The intended meaning of the term "secondary amine" is also clear from Schemes 2 and 4 on pages 12 and 13 and from Examples 3 and 6, all of which illustrate how the biguanide nitrogen reacts with an active group.

Although the specification does not specifically mention that a tertiary amino group remains in a bound biguanide residue, it is quite clear from the description that this must be the case. In particular, the description of the chemistry on pages 6-8 makes it clear that the nitrogen atom in the product must be a tertiary amine and this is shown even more clearly in the Scheme 2 on page 12, which shows the reaction of an isocyanate with the secondary amine of polyhexanide. It is clear that the polyhexanide nitrogen linked to the Infection Resistant Material (IRM) in the product is a tertiary amine (i.e. it has no hydrogen atoms attached to it). This is also made clear in Scheme 4 on page 13 and in the structures shown in Examples 3 and 6.

Thus, a monomer of the present invention where the biguanide-containing moiety is polyhexanide or a similar compound could take the form:



where, as with the Olstein patent, A is a polymerizable group and Q is a linker (urea, thiourea, etc). The polymerizable group A may be, for example, a methacrylate group as in Example 6).

On comparing this structure with that of the monomer of Olstein (shown above), it can be seen that in the <u>product</u> monomers and polymers of the present invention, the biguanide-containing moiety is linked to the monomer or to the polymer chain in such a way that a tertiary amine group remains in the bound residue of the biguanide moiety. This tertiary amine moiety is obtained by reacting a biguanide secondary amine moiety with a reactive group on the monomer or polymer.

In contrast, in the product of Olstein, the biguanide moiety is linked to the monomer or to the polymer chain via a secondary amine group in the residue of the biguanide moiety. This is obtained by reacting a biguanide-linker moiety with a monomer (see columns 7 and 8 of Olstein).

Therefore, the polymer defined in amended claim 39 is not anticipated by Olstein.

In addition, Applicant submits that the polymers of the present invention are advantageous over those of Olstein because they can incorporate chains of biguanide moieties (e.g. chlorhexidine or polyhexanide) rather than single biguanide moieties and thus the present invention represents a way of including a greater number of biguanide moieties in a polymer chain.

Similar amendments to that outlined above for claim 39 have been made to claims 41, 42, 45, 49 and 54. Thus, all of claims 39, 41, 43-45, 47-49, 51-54, 56-63 and 66 now specify that in the product, the biguanide-containing moieties are linked to the polymer chain in such a way that

a tertiary amino group remains in the biguanide residue. In view of the amendments to the claims, Applicant submits that none of the claims are now anticipated by Olstein.

Further, favorable reconsideration is also requested of the rejection of claims 39, 41, 46, 50 and 55 as being anticipated by GB1531717 (Buckley et al). It is submitted that the polymer of the present invention, as defined by the claims as amended herein, is entirely different from that of Buckley et al. Firstly, all of claims 39, 41, 46, 50 and 55 relate to a polymer in which the biguanide-containing moiety is pendant to the polymer chain. This is not the case with the polymers of Buckley et al., which are polymers in which the biguanide groups form part of the polymer backbone. This is clear from the structure on page 1 of the Buckley et al. document, where the polymers are described as having the structure:

X-BG-Y-BG

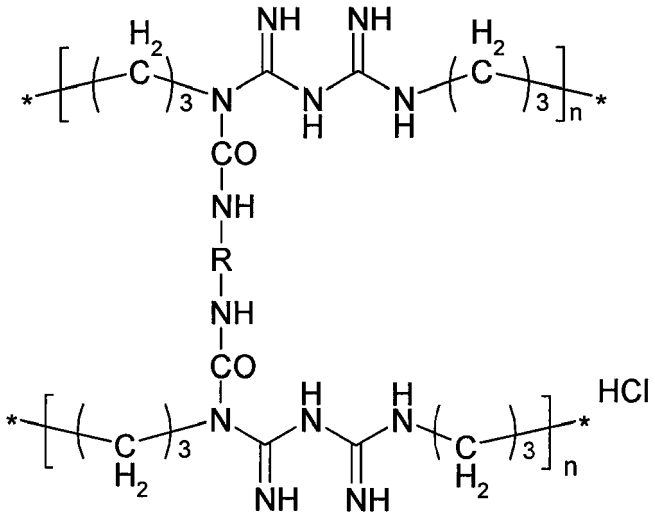
wherein BG is the biguanide group.

Furthermore, it is clear from the Buckley et al. document that in the polymers, the biguanide residues are linked in a chain via secondary amino groups. As discussed in more detail above, this is in contrast to the polymers of the present invention in which a bound biguanide residue is linked to the polymer chain via a tertiary amine group. Thus, none of the amended claims is anticipated by Buckley et al.

Favorable reconsideration is also requested of the rejection of claims 40, 42, 48, 64 and 65 as being unpatentable over Olstein and Solomon et al. (US 5,451,424). As discussed above, the amended claims clearly differentiate the compounds of the present invention from those of Olstein. Nothing in the Solomon et al. reference supplies the deficiencies of Olstein and therefore Applicant submits that the claims are not obvious over this combination of documents.

The Examiner's comments and responses to the previous arguments have been carefully considered and Applicants submit that the amendments submitted herewith take account of these comments and that therefore the amended claims are allowable.

Finally, it is noted that there is an error in the structure set out on page 17 of the specification where the C=O group is linked to the wrong part of the biguanide structure. The correct structure should be:



It would be quite clear to one of skill in the art that the structure is incorrect and that the correct structure is as shown above. Accordingly, amendment of the Specification in this regard has been requested.

In view of the foregoing, it is submitted that all claims of record define patentably over the art of record and are thus in allowable condition. Thus, favorable reconsideration and early allowance of all claims are earnestly solicited.

Respectfully submitted,

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